PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

June 20, 2007

Honorable Patti B. Saris
United States District Judge
United States District Court for the District of Massachusetts
1 Courthouse Way
Boston, MA 02210

Re: **New England Carpenters Health Benefits Fund, et al. v. First DataBank, Inc. and McKesson Corporation, Civil Action No. 05-11148-PBS; District Council 37 Health and Security Plan v. Medi-Span, Civil Action No. 07-CV-10988**

Dear Judge Saris:

We are writing on behalf of Pharmaceutical Care Management Association (PCMA) to share our substantial concerns regarding the proposed settlement in the above case proposed by Plaintiffs and Defendants First DataBank ("FDB") and Medi-Span. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. We are writing in anticipation of the preliminary fairness hearing now scheduled for June 21, 2007.

We intend this short letter to be helpful to the Court with regard to the fairness and reasonableness of the Proposed Settlement. In particular, the Settlement as currently structured (1) represents an overreaction to a largely non-existent problem which will impose unnecessary transaction costs on numerous entities, including much of the proposed Private Payor Class (the "Class"); (2) contains an unrealistic and unworkable definition of the Class that would require examination of individual PBM contracts to determine membership; and (3) requires PBMs to engage in unnecessary and potentially inappropriate pricing discussions with competitors and suppliers.

As this Court correctly noted at the May 22nd hearing, the Proposed Settlement here is "very unusual." (Trans. at p. 58) Plaintiffs allege a RICO "conspiracy" that they claim has cost 11,000 third party-payors billions of dollars; yet, for no monetary payment whatsoever by the defendants, the Proposed Settlement would grant FDB – and now Defendant Medi-Span -- a general release of the very claims that are at the core of this alleged fraudulent scheme. In short, the Proposed Settlement requires nothing of the principal alleged conspirators, FDB and Medispan. Instead, the Proposed Settlement appears designed to make public policy and "fix" a problem that market participants have already addressed.

* * *

1. The Proposed Settlement Attempts to Address an Issue that Has Been Largely Dealt With by the Marketplace

Thus, Plaintiffs make the simplistic, but incorrect, assumption that a "static" marketplace over the seven years since the Class Period began on January 1, 2000, failed to take account of alleged higher AWPs. Far from static, the PBM industry and its clients, the Class members, are highly sophisticated, operating in a competitive and dynamic marketplace.[1] Price changes – let alone the significant price changes alleged by the Plaintiffs -- do not go unnoticed or unaddressed by PBM clients, which include health benefit plans, self-insured employers, third-party administrators (TPA), and union-sponsored plans. No less an authority than the Federal Trade Commission has noted on many occasions the industry's "highly competitive" nature, with PBMs competing on both price dimensions (such as the reimbursement rate and dispensing fee paid to pharmacies, rebates paid to plan sponsors and mail order pricing), as well as non-price dimensions, such as plan design, how extensive the PBM's retail network is, and the availability and extent of mail order services. Federal Trade Commission and U.S. Department of Justice, "Improving Health Care: A Dose of Competition," ch. 7, at 15 (July 2004), ("Healthcare Report"), available at www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf. [2]

In this competitive marketplace, PBM clients – many in the Class -- are well aware of their numerous choices among the 40 to 50 PBMs operating in the country today, as they search for lower prescription drugs prices and additional services for plan members. Those sophisticated clients, often advised by consultants, possess an ongoing ability to bargain for contractual provisions regarding various discounts, rebates, fees and reimbursement formulas available. Although PBM contracts sometimes have a term of as long as three years, they often contain terms that allow pricing factors to be adjusted during that period; in any event, as a practical matter, clients are able to demand pricing concessions in response to market developments at any time. The result is that, over the Class Period, PBMs have been able to provide – and Class members have benefited from – increasingly deeper discounts in the mail service and retail channels, lower administrative and dispensing fees, and higher levels of manufacturer rebate-sharing. It is a fallacy to assume that AWP increases occurring in 2002 and 2003 have not been substantially, if not entirely, offset by marketplace forces in this highly competitive setting.

In short, PBM clients and other industry participants focus intently on prescription drug pricing, and adjust their contract terms accordingly. In this way, the marketplace for PBM services has already reacted to the changes effected over the course of the Class Period. As this Court recognized during the May 22, 2007, hearing on Plaintiffs' Motion for Class Certification

---

[1] During the seven-year Class Period, in fact, the highly competitive PBM industry has been extremely successful in keeping costs down for their clients *in the midst of Plaintiffs' alleged conspiracy to inflate drug prices*. As found in a recent Federal study, prescription drug-spending slowed to its lowest growth rate in 2005 in over a decade, with the 5.8% prescription–drug growth rate in 2005 representing a 33% reduction from the 2004 growth rate of 8.6%. The study credits some of the tools employed by PBMs, including tiered co-payment benefit plans and formularies, a continued shift to the use of generic drugs, and continued strong growth in mail-service pharmacies. Catlin, A., Cowan, C., et al., "National Health Spending in 2005: The Slowdown Continues," Health Affairs 142 (Jan. 2007). The authors are all with the Centers for Medicare and Medicaid Services, Office of the Actuary.

[2] This Court's own expert report from Dr. Ernst R. Berndt in the underlying AWP case also challenged the assumption that PBM competition was inadequate, and highlighted the "vigorous" competition among PBMs for the business of third-party payors. Report at 112-113.

in this matter, "as we all know, the PBMs and the consulting contracts all give a huge amount of knowledge and leverage to do push back. So within a year or two of the bump-up of the price, you've already seen adjustments." Transcript of May 22, 2007 Hearing, p.8, lines 6-10. Five years later, the fact of the increase in WAC to AWP spread has inevitably been part of contract negotiations between PBMs and their clients, as well as among other market participants, since that time. The increase has, in short, been bargained away.

While failing to remedy any existing injury or harm, the Proposed Settlement will only lead to yet another round of contract and pricing re-negotiations among marketplace participants – this time in response to the arbitrary and across-the-board price change effected by the Proposed Settlement. And with one of two results: (1) either the contract and pricing re-negotiations will be protracted and costly, with PBMs and retail pharmacies – who are not alleged to have participated in the alleged conspiracy – bearing the brunt of the costs of the reduction in the WAC to AWP spread; or (2) the re-negotiations will be relatively efficient, perhaps because existing contracts may allow for pricing modifications in response to an event like the Proposed Settlement, with class members receiving little to no benefit from the Proposed Settlement as a consequence. Either way, what is assured is that, while the Defendants – and alleged wrongdoers in the case – will pay nothing under the terms of this Proposed Settlement, industry participants who have done nothing wrong, who relied in good faith on AWP as a valid pricing benchmark in many of their contracts, and who have long since re-negotiated their contracts in response to the pricing changes that occurred in 2002 and 2003, will be forced to bear unnecessary transaction costs reacting to the Proposed Settlement. Such a result makes no sense.

2. Contract-by-Contract Review is Required to Determine Which PBM Contracts are Included in the Proposed Settlement Class

The Plaintiffs have demonstrated their misunderstanding of the PBM industry in defining the Class to include only those PBMs which are either "the fiduciary of the Third Party Payors" or which "by contract assumed, in whole or in part, the insurance risk of that prescription pharmaceutical benefit." (Updated Order Granting Preliminary Approval, dated June 6, 2007.)

Under this proposed definition, an individual PBM cannot simply be included or excluded as a whole from the Class. Rather, whether a particular PBM is within the scope of the new PBM carve-out depends on a relationship-by-relationship review of *every PBM contract with every client*. Thus, PBMs are not normally deemed "fiduciaries" for their external customers,[3] but in their role as plan sponsors are "fiduciaries" for their own employee benefit plans, including for administration of the prescription drug benefit. They can also in certain cases assume limited "fiduciary" responsibilities (for claims administration) by contract for a particular customer.[4]

---

[3] See *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005).

[4] We are assuming that Plaintiffs intend to define "fiduciary" consistently with the Employee Retirement Income Security Act (ERISA), which requires exercise of "any discretionary authority or discretionary control respecting management of such plan. .." 29 U.S.C. § 1002(21)(A).

Finally, since both health insurers and retail pharmacies are considered Class members without the exceptions created for PBMs, the result will be that a parent health insurer that has a subsidiary or affiliated PBM will be considered a member of the class but the affiliated PBM may not be except as to certain contracts. Thus, a given health insurer itself may be included [5] but not its subsidiary PBM, unless for particular contracts that PBM meets the criteria specified in the Settlement, namely acting as a "fiduciary" or "assum[ing] the insurance risk." Since the definition makes no distinction between risk-bearing and non-risk bearing health insurance contracts, the result will be to include TPAs which receive administrative fees for performing services to a benefit plan without bearing any "insurance risk."

In sum, in order to determine whether its contracts are within the scope of the proposed settlement class, each PBM must engage in a contract-by-contract determination as to whether it is included in the proposed Class with respect to particular contracts. That determination may be cumbersome and costly; adding additional concerns regarding the burden imposed by what PBMs believe is an unnecessary and counter-productive Settlement.

3. The Proposed Settlement Inappropriately Mandates that PBMs Engage in Court-Ordered Pricing Discussions with Competitors and Suppliers

The difficulties created for PBMs by the Proposed Settlement are further illustrated by an additional provision in the document which purports to require PBMs to participate in highly sensitive pricing discussions with competitors, suppliers, and customers alike. That provision, in section (5), entitled "Mediation," asks this Court to order the multiple entities engaged in the pharmaceutical chain, whether as manufacturers, buyers, or sellers, to participate:

> *in a Settlement Court-approved mediation process meant to facilitate the establishment of a sustainable benchmark for pharmaceutical reimbursement.*

In essence, this provision seeks to transform this Court into a regulator and imposes a one-size-fits all standard that would make the marketplace less rather than more competitive. It is especially inappropriate as applied to PBMs, which relied in good faith on the AWPs as reported by Defendant FDB and other publishers, and are nowhere alleged to have engaged in any manner in the claimed RICO conspiracy. The PBM industry is as successful as it is in lowering prices of pharmaceuticals because it bargains aggressively with both pharmaceutical manufacturers of brand-name and generic drugs as well as with retail pharmacy networks for distribution of those drugs. The marketplace already has made room for myriad measures of pharmaceutical pricing, measures which allow the many competitors to work with customers to choose measures and alternatives that work for them.

* * *

PCMA believes that any drug price benchmark, whether AWP, AMP, WAC or any other measure, should be both an accurate reflection of pharmaceutical sales transactions, as well as

[5] This analysis is equally applicable to health insurers which contract on an "administrative services only" basis, assuming no pricing risk, as is often the case with self-insured customers.

broad enough to protect the highly individualized nature of drug price negotiations between both PBMs and their customers as well as between PBMs and pharmaceutical manufacturers. We also believe that benchmark should be flexible enough to foster the enormous variety and contractual diversity that now exists in the PBM industry, thus allowing what the FTC terms "vigorous competition" in the PBM market sector to flourish. This Proposed Settlement meets none of those tests, and instead seriously disrupts the industry while imposing unjustifiable costs and burdens on both PBMs and their clients – the class members – who are not alleged to have participated in the alleged unlawful conduct.

We thank the Court for considering our comments.

Respectfully,

Mark Merritt
CEO and President
Pharmaceutical Care Management Association

c: *Counsel for Plaintiffs*

Thomas M. Sobol
Hagens Berman Sobol Shapiro LLP
One Main Street
Cambridge, MA 02142

Counsel for Medi-Span

Sheldon Zenner
Katten Muchin
525 West Monroe Street
Chicago, IL 60661-3693

Kevin E. Sharkey
66 Bay Street
Manchester, NH 03104

Counsel for First DataBank

Sheila L. Birnbaum
Skadden Arps Slate Meagher & Flom LLP
Four Times Square
New York, NY 10036-6522

Counsel for McKesson

Lori A. Schechter
Morrison & Forrester
425 Market Street
San Francisco, CA 94105-2482